## Title 25 ARTICLE 5, PART 4 PURE FOOD AND DRUG LAW

25-5-401	Short Title	25-5-414	Adulterations (drug or device)
25-5-402	Definitions	25-5-415	Misbranding (drug or device)
25-5-403	Offenses	25-5-416	Adulteration of cosmetics
25-5-404	Injunction	25-5-417	Misbranding of cosmetics
25-5-405	Penalties	25-5-418	Advertisements
25-5-406	Tagging articles misbranded or	25-5-419	Packaging and labeling of
	adulterated		consumer commodities
25-5-407	Duties of district attorney	25-5-420	Enforcement
25-5-408	Discretion as to warning	25-5-421	Inspections
25-5-409	Regulations	25-5-422	Reports and information
25-5-410	Definitions of "adulterated" (food)	25-5-423	Cooperation with federal agencies
25-5-411	Definitions of "misbranding" (food)	25-5-424	Review
25-5-412	Issuance of permits	25-5-425	Application of part 4
25-5-413	Limit of adulteration - rule or		
	regulation		

25-5-401. SHORT TITLE. This part 4 shall be known and may be cited as the "Colorado Food and Drug Act."

25-5-402. DEFINITIONS. As used in this part 4, unless the context otherwise requires:

- (1) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.
  - (2) "Color" includes black, white, and intermediate grays.
  - (3) (a) "Color additive" means a material which:
- (I) Is a dye, pigment or other substance made by a process of synthesis or similar artifice or extracted, isolated, or otherwise derived, with or without intermediate or final change of identify, from a vegetable, animal, mineral or other source; and
- (II) When added or applied to a food, drug, or cosmetic or to the human body or any part thereof; is capable (alone or through reaction with other substance) of imparting color thereto; except

that such term does not include any material which is exempted under the federal act.

- (b) Nothing in this subsection (3) shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process or produce of the soil and thereby affecting its color, whether before or after harvest.
- (4) "Consumer commodity", except as otherwise specifically provided in this subsection (4), means any food, drug, cosmetic, or device. Such term does not include:
  - (a) Any tobacco or tobacco product;
- (b) Any commodity subject to packaging or labeling requirements imposed under article 9 of title 35, CRS 1973, being known as the "Pesticide Act", or imposed by the Secretary of Agriculture under the "Federal Insecticide, Fungicide, and Rodenticide Act", as amended (7 U.S.C. 135-135k), or under the federal "Animal Virus, Serum, Toxin, Antitoxin Act" (21 U.S.C. 151-158);
- (c) Any drug subject to the provisions of section 25-5-415 (1) (m) or of 21 U.S.C. 353 (b) (1) or 356;
- (d) Any beverage subject to or complying with packaging or labeling requirements imposed under the "Federal Alcohol Administration Act" (27 U.S.C.201-211); or
- (e) Any commodity subject to the provisions of article 27 of title 35, C.R.S. 1973, concerning seeds.
- (5) "Contaminated with filth" applies to any food, drug, cosmetic, or device not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.
- (6) "Cosmetic" means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance or articles intended for use as a component of any such articles; except that such term does not include soap.
  - (7) "Department" means the department of health.
  - (8) "Device", except when used in subsection (23) of this section and in sections 25-5-403 (1)

- (j), 25-5-411 (1) (g), 25-5-415 (i) (d), and 25-5-417 (1) (d), means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or to affect the structure or any function of the body of man or other animals.
  - (9) "Drug" means:
- (a) Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them;
- (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- (c) Articles, other than food, intended to affect the structure or any function of the body of man or other animals;
- (d) Articles intended for use as a component of any article specified in paragraphs (a), (b), or (c) of this subsection (9) but does not include devices or their components, parts, or accessories.
- (10) "Federal act" means the "Federal Food, Drug, and Cosmetic Act" (Title 21 U.S.C. 301 et seq., 52 Stat. 1040 et seq.).
- (11) "Food" means articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.
- (12) "Food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and including any source of radiation intended for any such use) if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. The term does not include:
  - (a) A pesticide chemical in or on a raw agricultural commodity;
- (b) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;

## (c) A color additive; or

- (d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the amendment to the federal act known as the "Food Additives Amendment of 1958", the "Poultry Products Inspection Act" (21 U.S.C. 451-470), or the "Meat Inspection Act of March 4, 1907", as amended and extended (21 U.S.C. 71-91).
  - (13) "Immediate container" does not include package liners.
- (14) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and by or under the authority of this part 4 a requirement that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.
- (15) "Labeling" means all labels and other written, printed, or graphic matter upon an article or any of its containers or wrappers, or accompanying such article.
- (16) "Official compendium" means the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them.
- (17) "Package" means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers. The term does not include:
- (a) Shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; or
- (b) Shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers or wrappers bear no printed matter pertaining to any particular commodity.
  - (18) "Person" includes an individual, partnership, corporation, and association.
- (19) "Pesticide chemical" means any substance which alone, in chemical combination, or in formulation with one or more other substances is a pesticide within the meaning of section 35-9-102 (21),

- C.R.S. 1973, and which is used in the production, storage, or transportation of raw agricultural commodities.
- (20) "Principal display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.
- (21) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.
- (22) "Safe", as used in subsection (12) of this section, has reference to the health of man or animal.
- (23) If an article is alleged to be misbranded because the labeling is misleading or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account all representations made or suggested by statement, work, design, device, sound, or any combination thereof, and also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.
- (24) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as being, an antiseptic for inhibitory use which involves prolonged contact with the body.
- (25) The provisions of this part 4 regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article; and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.
- 25-5-403. OFFENSES. (1) The following acts and the causing thereof within this state are prohibited:
- (a) The manufacture, sale, or delivery or the holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
  - (b) The adulteration or misbranding of any food, drug, device, or cosmetic;

- (c) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded and the delivery or proffered delivery thereof for pay or otherwise;
- (d) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 25-5-412:
  - (e) The dissemination of any false or misleading advertisement;
- (f) The refusal to permit entry, inspection, or the taking of a sample, as authorized by section 25-5-421;
- (9) The giving of a false guaranty or undertaking except by a person who relied on a guaranty or undertaking to the same effect signed by and containing the name and address of the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic;
  - (h) The removal or disposal of a detained or embargoed article in violation of section 25-5-406;
- (i) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of or the doing of any other act with respect to a food, drug, device, or cosmetic which results in such article being adulterated or misbranded, if such act is done while such article is being stored or held for sale:
- (j) Forging, counterfeiting, simulating, falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device required by this part 4 or by regulations promulgated under the provisions of this part 4;
- (k) The distribution or causing to be distributed in commerce of any consumer commodity if such commodity is contained in a package or if there is affixed to that commodity a label which does not conform to the provisions of this part 4 and of regulations promulgated pursuant to this part 4; except that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:
  - (I) Are engaged in the packaging or labeling of such commodities; or
- (II) Prescribe or specify by any means the manner in which such commodities are packaged or labeled;
- (1) The using by any person to his own advantage or the revealing, other than to the executive director of the department or his authorized representative or to the courts, when relevant in any judicial proceeding under this part 4, of any information acquired under authority of this part 4 concerning any

method or process which as a trade secret is entitled to protection.

- 25-5-404. INJUNCTION. In addition to the remedies provided in this part 4, the department is authorized to apply to the district court of the district where-in the defendant resides or has his place of business for, and such court shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of section 25-5-403, irrespective of whether or not there exists an adequate remedy at law.
- 25-5-405. PENALTIES. (1) Any person who violates any of the provisions of section 25-5-403 is guilty of a misdemeanor and upon conviction thereof, shall be punished by a fine of not more than one thousand dollars, or by imprisonment in the county jail for not more than six months, or by both such fine and imprisonment; but, if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to a fine of not more than two thousand dollars, or to imprisonment for not more than one year, or to both such fine and imprisonment for each succeeding offense. Each violation shall be considered a separate offense.
- (2) No person shall be subject to the penalties of subsection (1) of this section for having violated section 25-5-403 (1) (a) or (1) (c) if he establishes a valid guaranty or undertaking signed by and containing the name and address of the person residing in the United States from whom he received in good faith the article to the effect that such article is not adulterated or misbranded within the meaning of this part 4, designating this part 4.
- (3) No publisher, radio-broadcast licensee, television licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement unless he refuses, on the request of the department, to furnish the department the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the United States who caused him to disseminate such advertisement.
- 25-5-406. TAGGING ARTICLES MISBRANDED OR ADULTERATED. (1) Whenever a duly authorized agent of the department finds or has probable cause to believe that any food, drug, device, or cosmetic is adulterated or misbranded within the meaning of this part 4, he shall affix to such article a tag or other appropriate marking giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the department or such agent or the court. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the department or its agent or, after summary proceedings have been instituted, without permission from the court. If the embargo is removed by the department or by the court, neither the department nor the state shall be held liable for damages because of such

embargo in the event that the court finds that there was probable cause for the embargo.

- (2) When an article detained or embargoed under subsection (1) of this section has been found by such agent to be adulterated or misbranded, he shall petition the judge of the district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. When such agent finds that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.
- (3) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of such agent, and all court costs and fees and storage and other proper expense shall be taxed against the claimant of such article or his agent; except that, when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of an agent of the department. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article on representation to the court by the department that the article is no longer in violation of this part 4 and that the expenses of such supervision have been paid.
- (4) Whenever the department or any of its authorized agents find in any room, building, vehicle of transportation, or other structure any meat, seafood, poultry, vegetable, fruit, or other perishable articles which are unsound or contain any filthy, decomposed, or putrid substance or which may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department or its authorized agent shall forthwith condemn or destroy the same or in any other manner render the same unsaleable as human food.
- 25-5-407. DUTIES OF DISTRICT ATTORNEY. It is the duty of each district attorney to whom the department reports any violation of this part 4 to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.
- 25-5-408. DISCRETION AS TO WARNING. Nothing in this part 4 shall be construed as requiring the department to report, for the institution of proceedings under this part 4, minor violations of this part 4 whenever the department believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.
- 25-5-409. REGULATIONS. (1) Definitions and standards of identity, quality, and fill of container for any food adopted under authority of the federal act are the definitions and standards of identity, quality, and fill of container in this state. However, when, in its judgment, such action will promote honesty and fair dealing in the interest of consumers, the department may promulgate additional

regulations establishing definitions and standards of identity, quality, and fill of container for foods which are not subject to any federal regulations. Any definition or standard of identity, quality, or fill of container promulgated under this subsection (1) which is in addition to federal definitions and standards shall constitute a regulation of the department, and it shall be subject to the requirements of section 25-5-420 concerning the procedures for promulgating such regulations. The department may promulgate amendments to any federal or state regulations which set definitions and standards of identity, quality, and fill of container for foods in the same manner as is provided for their adoption.

- (2) Temporary permits granted under the federal act for interstate shipment of experimental packs of food varying from the requirements of federal definitions and standards of identity are automatically effective in this state under the conditions provided in such permits. The department may issue additional permits if they are necessary to the completion or conclusiveness of an otherwise adequate investigation and if the interests of consumers are safeguarded. Such permits are subject to the terms and conditions the department may prescribe by regulation.
- 25-5-410. DEFINITIONS OF "ADULTERATED" (FOOD). (1) A food is deemed to be adulterated:
- (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but, in case the substance is not an added substance, such food shall not be considered adulterated under this paragraph (a) if the quantity of such substance in such food does not ordinarily render it injurious to health;
- (b) (I) If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 25-5-413; except that a pesticide chemical in or on a raw agricultural commodity, a food additive, or a color additive shall not be deemed a poisonous or deleterious substance within the meaning of this paragraph (b);
- (II) If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 25-5-413 (1); but, if a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 25-5-413
- (2) and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food, notwithstanding the provisions of section 25-5-413 (1) and this subparagraph (II), shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or

- (III) If it is, or it bears or contains any food additive which is, unsafe within the meaning of section 25-5-413 (1);
- (c) If it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance or if it is otherwise unfit for food;
- (d) If it is produced, prepared, packed, or held under unsanitary conditions whereby it may be contaminated with filth or rendered diseased, unwholesome, or injurious to health;
- (e) If it is, in whole or in part, the product of a diseased animal or an animal which has died otherwise than by slaughter or which has been fed upon the uncooked offal from a slaughterhouse;
- (f) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (9) If it has been intentionally subjected to radiation unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 25-5-413 or 21 U.S.C. 348;
  - (h) (I) If any valuable constituent has been in whole or in part omitted or abstracted therefrom;
  - (II) If any substance has been substituted wholly or in part therefor;
  - (III) If damage or inferiority has been concealed in any manner;
- (IV) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;
  - (i) If it is confectionery and:
- (I) Has partially or completely imbedded therein any nonnutritive object; but this subparagraph (I) shall not apply in the case of any nonnutritive object if in the judgment of the department as provided by regulations, such object is of practical functional value to the confectionery product and does not render the product injurious or hazardous to health;
- (II) Bears or contains any alcohol other than alcohol not in excess of one-half of one percent by volume derived solely from the use of flavoring extracts; or
  - (III) Bears or contains any nonnutritive substance; but this subparagraph (III) shall not apply to a

safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this part 4; and, furthermore, the department, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph (III), may issue regulations allowing or prohibiting the use of particular non-nutritive substances;

- (j) If it is, or it bears or contains a color additive which is, unsafe within the meaning of section 25-5-413 (1) or the federal act;
- (k) If it is chopped or ground beef or hamburger and it contains any meat other than the voluntary striated muscle of beef, or the total fat content, derived solely from beef, is in excess of thirty percent, or it contains any substance other than those which the department has by regulation declared to be permitted optional ingredients.;
- (1) If it is fresh meat or a fresh meat product, or fresh poultry, parts thereof, or fresh poultry products, and contains any antiseptic or chemical preservative;
- (m) If it is meat or a meat product and contains any artificial coloring or if it is contained in an artificially colored casing or wrapper; except that the department may by regulation establish the conditions of the use of artificial color in casings and wrappers;
- (n) If it is pork sausage or pork breakfast sausage and the total fat content is in excess of fifty percent.
- 25-5-411. DEFINITIONS OF "MISBRANDING" (FOOD). (1) A food shall be deemed to be misbranded:
  - (a) If its labeling is false or misleading in any particular;
  - (b) If its labeling or packaging fails to conform to the requirements of section 25-5-419;
  - (c) If it is offered for sale under the name of another food;
- (d) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated;
  - (e) If its container is so made, formed, or filled as to be misleading;

- (f) If in package form, unless it bears a label containing;
- (I) The name and place of business of the manufacturer, packer, or distributor; and
- (II) An accurate statement of the net quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label; but, as to such terms of quantity, reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulation prescribed by the department;
- (9) If any word, statement, or other information required by or under authority of this part 4 to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (h) If it purports to be or is represented as a food for which a definition and standard of identity is prescribed by regulations as provided by section 25-5-409, unless it conforms to such definition and standard and its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;
  - (i) If it purports to be or is represented as:
- (I) A food for which a standard of quality has been prescribed by regulations as provided by section 25-5-409 and its quality falls below such standard, unless its label bears, in such manner and form as regulations specify, a statement that it falls below such standard; or
- (II) A food for which a standard of fill of container is prescribed by regulations as provided by section 25-5-409 and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;
- (j) If it is not subject to the provisions of paragraph (h) of this section, unless it bears labeling clearly giving the common or usual name of the food, if any, and, if it is fabricated from two or more

ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each; but, to the extent that compliance with the requirements as to such multiple names is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the department. The requirements of this paragraph (j) shall not apply to food products which are packaged at the direction of purchasers at retail at the time of sale whose ingredients are

disclosed to the purchasers by other means in accordance with regulations promulgated by the department.

- (k) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the department determines to be and by regulations prescribes as necessary in order to fully inform purchasers as to its value for such uses;
- (1) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; but, to the extent that compliance with the requirements of this paragraph (1) is impracticable, exemptions shall be established by regulations promulgated by the department. The provisions of this paragraph (1) and paragraphs (h) and (j) of this subsection (1) with respect to artificial coloring do not apply to butter, cheese, or ice cream. The provisions of this paragraph (1) with respect to chemical preservatives do not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.
- (m) If it is a product intended as an ingredient of another food and, when used according to the directions of the purveyor, will result in the final food product being adulterated or misbranded;
- (n) If it is meat imported from without the boundaries of the United States or if it is a meat product containing such meat, unless it bears labeling stating the fact that it is imported meat or that it contains imported meat. Any person who sells or offers for sale in this state any meat imported from without the boundaries of the United States, or any meat product containing such imported meat, without labeling such meat or meat product stating that it is imported, or contains imported meat, is guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than one hundred dollars nor more than one thousand dollars, or by imprisonment in the county jail for not less than thirty days nor more than ninety days, or by both such fine and imprisonment.
- (o) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or

usual name and the function of such chemical; except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade;

(p) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive as may be contained in regulations

issued pursuant to the provisions of the federal act.

- (2) Foods which, in accordance with the practice of the trade, are to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling requirements under this section if such food is not adulterated or misbranded under any provision of this part 4 upon removal from such processing, labeling, or repacking establishment. Regulations adopted under authority of the federal act (21 U.S.C. 345) relating to such exemptions are automatically effective in this state. The department may promulgate additional regulations or amendments to existing regulations concerning such exemptions, but the department may not promulgate any regulation which has the effect of allowing any food which is subject to federal labeling requirements to be exempt from labeling requirements under the law of this state.
- 25-5-412. ISSUANCE OF PERMITS. (1) Whenever the department finds after investigation that the distribution in this state of any class of food may, by reason of contamination with microorganisms during manufacture, processing, or packing thereof in any locality, be injurious to health and that such injurious nature cannot be adequately determined after such articles have entered commerce, it, then and in such case only, shall promulgate regulations providing for the issuance to manufacturers, processors, or packers of such class of food in such locality of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food for such temporary period of time as may be necessary to protect the public health; and, after the effective date of such regulations and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer, unless such manufacturer, processor, or packer holds a permit issued by the department as provided by such regulations.
- (2) The department is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged to apply at any time for the reinstatement of such permit, and the department shall, immediately after prompt hearing and inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit as originally issued or as amended.
- (3) Any officer or employee duly designated by the department shall have access to any factory or establishment, the operator of which holds such a permit from the department, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be grounds for suspension of the permit until such access is freely given by the operator.

- 25-5-413. LIMIT OF ADULTERATION RULE OR REGULATION. (1) Any added poisonous or deleterious substance, food additive, pesticide chemical in or on a raw agricultural commodity, or color additive, with respect to any particular use or intended use, shall be deemed unsafe for the purpose of application of section 25-5-410 (1) (b) with respect to any food, section 25-5-414 (1)(a) to (l)(f) with respect to any drug or device, or section 25-5-416 (l)(a) with respect to any cosmetic, unless there is in effect a regulation pursuant to section 25-5-419 or subsection (2) of this section limiting the quantity of. such substance and the use or intended use of such substance is within the limits prescribed by such regulation. While such a regulation relating to such substance is in effect, a food, drug, or cosmetic, by reason of bearing or containing such substance in accordance with the regulations, shall not be considered adulterated within the meaning of section 25-5-410 (l)(b), 25-5-414 (1)(a) to (l)(f), or 25-5-416 (l)(a).
- (2) The department, whenever public health or other considerations so require, is authorized to adopt, amend, or repeal regulations upon its own motion or upon the petition of any interested party, whether or not in accordance with regulations promulgated under the federal act. Such regulations may prescribe tolerances for any added poisonous or deleterious substances, food additives, pesticide chemicals in or on raw agricultural commodities, or color additives, including but not limited to zero tolerances. The department may prescribe exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities. The department may also promulgate regulations prescribing the conditions under which a food additive or a color additive may be safely used and exemptions if such food additive or color additive is to be used solely for investigational or experimental purposes. It shall be incumbent upon any petitioner to establish that a necessity exists for such regulation and that its effect will not be detrimental to the public health. If the data furnished by the petitioner are not sufficient to allow the department to determine whether such regulation should be promulgated, the department may require additional data to be submitted, and failure to comply with the request shall be sufficient grounds for denial of the request. In adopting, amending, or repealing regulations under this section, the department shall consider, among other relevant factors, the following, which the petitioner, if any, shall furnish:
- (a) The name and all pertinent information concerning such substance, including, where available, its chemical identity and composition; a statement of the conditions of the proposed use,

including directions, recommendations, suggestions, and specimens of proposed labeling; all relevant data bearing on the physical or other technical effects; and the quantity required to produce such effect;

- (b) The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of such substance;
  - (c) The probable consumption of such substance in the diet of man and animals taking into

account any chemically or pharmacologically related substance in such diet;

- (d) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;
- (e) The availability of any needed practicable methods of analysis for determining the identity and quantity of:
  - (I) Such substance in or on an article;
  - (II) Any substance formed in or on such article because of the use of such substance; and
  - (III) The pure substance and all intermediates and impurities;
- (f) Facts supporting a contention that the proposed use of such substance will serve a useful purpose.
- 25-5-414. ADULTERATIONS (DRUG OR DEVICE). (1) A drug or device shall be deemed to be adulterated:
  - (a) If it consists in whole or in part of any filthy, putrid, or decomposed substance;
- (b) If it has been produced, prepared, packed, or held under unsanitary under which it may have been contaminated with filth or rendered in-health;
- (c) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this part 4 as to safety and that such drug has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.
- (d) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (e) If it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act or section 25-5-413 (1);

- (f) If it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the federal act or section 25-5-413 (1);
- (g) If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium or, in case of the absence or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph (g) because it differs from the standard of strength, quality, or purity therefor set forth in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia.
- (h) If it is not subject to the provisions of paragraph (g) of this sub-section (1) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;
- (I) If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefor.
- 25-5-415. MISBRANDING (DRUG OR DEVICE). (1) A drug or device shall be deemed to be misbranded:
  - (a) If its labeling is false or misleading in any particular;
- (b) If its labeling or packaging fails to conform with the requirements of section 25-5-419;
  - (c) If in package form, unless it bears a label containing:
  - (I) The name and place of business of the manufacturer, packer, or distributor; and
- (II) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in uniform location upon the principal display panel of the label, except as exempted by section 25-5-402 (4)(c); but, as to

such terms of quantity, reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulation prescribed by the department or issued under the federal act;

(d) If any word, statement, or other information required by or under authority of the part 4 to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

## (e) (I) If it is a drug, unless:

- (A) Its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), the established name, as defined in subparagraph (II) of this paragraph (e), of the drug, if such there be; and, in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein; except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this sub-subparagraph (A), shall apply only to prescription drugs; and
- (B) For any prescription drug, the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient. To the extent that compliance with the requirements of this sub-subparagraph (B) and sub-subparagraph (A) of this subparagraph (I) as to fabricated drugs is impracticable, exemptions shall be established by regulations promulgated by the department or under the federal act.
- (II) As used in this paragraph (e), the term "established name", with a drug or ingredient thereof, means:
  - (A) The applicable official name designated pursuant to the federal act; or
- (B) If there is no such name and such drug or such ingredient is an article recognized in an official compendium, then the official title thereof in such compendium; or

- (C) If neither sub-subparagraph (A) nor sub-subparagraph (B) of this sub-paragraph (II) applies, then the common or usual name, if any, of such drug or of such ingredient;
- (D) Where sub-subparagraph (B) of this subparagraph (II) applies to an article recognized in the United States pharmacopoeia and in the homeopathic pharmacopoeia under different official titles, the official title used in the United States pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the homeopathic pharmacopoeia shall apply.
- (f) Unless its labeling bears adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; but, where any requirement as to such adequate directions for use, as applied to any drug or device, is not necessary for the protection of the public health, the department shall promulgate regulations exempting such drug or device from such requirement, and articles exempted under regulations issued under the federal act shall also be exempt;
- (g) If it purports to be a drug, the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; but the method of packing may be modified with the consent of the department or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia. In the event of inconsistency between the requirements of this paragraph (g) and those of paragraph (e) of, this subsection (1) as to the name by which the drug or its ingredients are designated, the requirements of paragraph (e) of this subsection (1) shall prevail.
- (h) If it is found by the department or under the federal act to be a drug liable to deterioration, unless it is packaged in such form and manner and its label bears a statement of such precautions as the regulations issued by the department or under the federal act require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body has failed within a reasonable time to prescribe such requirements.

- (i) (I) If it is a drug and its container is so made, formed, or filled as to be misleading; or
- (II) If it is an imitation of another drug; or
- (III) If it is offered for sale under the name of another drug;
- (j) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;
- If its labeling represents it to have any effect in albuminuria, appendicitis, (k) arteriosclerosis, arthritis, baldness, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, rheumatism, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid; uremia, or venereal disease,, and shall also be deemed to be false; except that no labeling in violation of paragraphs (a) and (b) of this subsection (1) shall be deemed to be false under this paragraph (k) if it is disseminated only to members of the medical, dental, chiropractic, or veterinary professions or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; but, if the department determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named in this paragraph (k), the department shall by regulation authorize the labeling of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interests of public health; except that this paragraph (k) shall not be construed as indicating that self-medication for any disease is safe or efficacious:
- (1) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine,

codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as habit-forming by regulations issued by the department or pursuant to the federal act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning-May be habit-forming.";

(m) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless:

- (I) It is from a batch with respect to which a certificate or release has been issued pursuant to the federal act; and
  - (II) Such certificate or release is in effect with respect to such drug;
- (n) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphehicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless:
- (I) It is from a batch with respect to which a certificate or release has been issued pursuant to the federal act; and
- (II) Such certificate or release is in effect with respect to such drug; but this subparagraph (II) shall not apply to any drug or class of drugs exempted by regulations promulgated under the federal act. For the purpose of this paragraph (n), "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).
- (o) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of section 25-5-413 (2) or of the federal act;
- (p) In the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes, in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug, a true statement of:
- (I) The established name, as defined in paragraph (e)(II) of this subsection (1), printed prominently and in type at least half as large as that used for any trade or brand name thereof;
- (II) The formula showing quantitatively each ingredient of such drug to the extent required for labels under the federal act; and
- (III) Such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act;

- (q) If a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.
- (2) A drug sold on a prescription given by a member of the medical, dental, or veterinary profession (except a drug sold in the course of the conduct of a business of selling drugs pursuant to diagnosis by mail) shall be exempt from the requirements of this section if such member of the medical, dental, or veterinary profession is authorized by law to administer such drug or if such drug bears a label containing the name and place of business of the seller, the serial number and date of such prescription, the name of such member of the medical, dental, or veterinary profession, and, if stated in the prescription, the name of the patient, the directions for use, and any cautionary statements contained in such prescription.
- (3) Drugs and devices which, in accordance with the practice of the trade, are to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this part 4 if such drugs and devices are being delivered, manufactured, processed, labeled, repacked, or otherwise held in compliance with regulations issued by the department or under the federal act.

## 25-5-416. ADULTERATION OF COSMETICS. (1) A cosmetic shall be deemed to be adulterated:

- (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual. This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution This product contains ingredients which may cause skin irritations on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness." The label shall also bear adequate directions for such preliminary testing. For the purposes of this paragraph (a) and paragraph (e) of this subsection (1), "hair dye" does not include eyelash dyes or eyebrow dyes.
  - (b) If it consists in whole or in part of any filthy, putrid, or decomposed substance;
- (c) If it is produced, prepared, packed, or held under unsanitary conditions under which it may become contaminated with filth or rendered injurious to health;
- (d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
  - (e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe

within the meaning of the federal act or section 25-5-413 (1).

- 25-5-417. MISBRANDING OF COSMETICS. (1) A cosmetic shall be deemed to be misbranded:
  - (a) If its labeling is false or misleading in any particular;
- (b) If its labeling or packaging fails to conform with the requirements of section 25-5-419;
- (c) If in package form, unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label; but, as to such terms of quantity required, reasonable variations shall be permitted and exemptions as to small packages shall be established by regulation prescribed by the department or under the federal act;
- (d) If any word, statement, or other information required by or under authority of this, part 4 to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
  - (a) If its container is so made, formed, or filled as to be misleading;
- (f) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed in regulations under the provisions of the federal act. This paragraph (f) shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes as defined in section 25-5-416 (1) (a).
- (2) A cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed is exempted from the affirmative labeling requirements of this part 4 while it is in transit in commerce from one establishment to the other if such transit is made in good faith for such completion purposes only; but such cosmetic is otherwise subject to all applicable provisions of this part 4.
- 25-5-418. ADVERTISEMENTS. (1) An advertisement of a food, drug, device, or cosmetic is deemed to be false if it is false or misleading in any particular.

- For the purpose of this part 4, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, arthritis, baldness, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyalitis (infantile paralysis), prostate gland disorders, pyalitis, rheumatism, scarlet fever, sexual impotence, sinus infection; smallpox, tuberculosis, tumors, typhoid, uremia, or venereal diseases shall also be deemed to be false; except that no advertisement not in violation of subsection (1) of this section shall be deemed to be false under this subsection (2) if it is disseminated only to members of the medical, dental, chiropratic, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; but, if the department determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named in this subsection (2), the department shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interests of public health; except that this subsection (2) shall not be construed as indicating that self-medication for any diseases is safe or efficacious.
- 25-5-419. PACKAGING AND LABELING OF CONSUMER COMMODITIES. (1) All labels of consumer commodities, as defined in section 25-5-402 (4), shall conform with the requirements for the declaration of net quantity of contents of the federal "Fair Packaging and Labeling Act" (15 U.S.C. 1453) and the regulations promulgated pursuant thereto; but consumer commodities exempted from such requirements of the federal "Fair Packaging and Labeling Act" (15 U.S.C. 1451-1461) shall also be exempt from this subsection (1).
- (2) The label of any package of a consumer commodity which bears a representation as to the number of servings of such commodity contained in such package shall bear a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving.
- (3) No person shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or phrases appear in conjunction with the separate statement of the net quantity of contents required by subsection (1) of this section, but nothing in this subsection (3) shall prohibit supplemental statements, at other places on the package, describing in non-deceptive terms the net quantity of contents; but such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package.
- (4) (a) Whenever the department determines that regulations containing prohibitions or requirements other than those prescribed by subsection (1) of this section are necessary to prevent

the deception of consumers or to facilitate value comparisons as to any consumers commodity, the department shall promulgate with respect to that commodity regulations effective to:

- (I) Establish and define standards for the characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such consumer commodity, but this subparagraph (I) shall not be construed as authorizing any limitation on the size, shape, weight, dimensions, or number of packages which may be used to enclose any consumer commodity;
- (II) Regulate the placement upon any package containing any consumer commodity, or upon any label affixed to such consumer commodity, of any printed matter stating or representing by implication that such consumer commodity is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to purchasers there-of by reason of the size of that package or the quantity of its contents;
- (III) Require that the label on each package of a consumer commodity bear the common or usual name of such consumer commodity, if any, and, in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this subparagraph (III) shall be deemed to require that any trade secret be divulged; or
  - (IV) Prevent the nonfunctional slack-fill of packages containing consumer commodities.
- (b) For the purposes of subparagraph (IV) of paragraph (a) of this subsection (4), a package shall be deemed to be nonfunctionally slack-filled if it is filled to substantially less than its capacity for reasons other than protection of the contents of such package or the requirements of machines used for enclosing the contents in such package; except that the department may adopt any regulations promulgated pursuant to the federal "Fair Packaging and Labeling Act" (15 U.S.C. 1451-1461) which shall have the force and effect of law in this state.
- 25-5-420. ENFORCEMENT. (1) The authority to promulgate regulations for the efficient enforcement of this part 4 is vested in the department. The department is authorized to make the regulations promulgated under this part 4 conform, insofar as practicable, with those promulgated under the federal act, the federal "Fair Packaging and Labeling Act" (15 U.S.C. 1451-1461), and the federal "Meat Inspection Act of March 4, 1,907", as amended (21 U.S.C. 71-91). All regulations promulgated under this part 4 shall be promulgated in accordance with the provisions of article 4 of title 24, C.R.S. 1973.
- (2) Hearings authorized or required by this part 4 or by article 4 of title 24, C.R.S. 1973, shall be conducted by the department or such officer, agent, or employee as the department may

designate for the purpose.

- (3) All pesticide chemical regulations and their amendments adopted under authority of the federal act are the pesticide chemical regulations in this state. However, the department may adopt regulations which prescribe tolerances for pesticides in finished foods in this state which are no less stringent than regulations promulgated under the federal act.
- (4) All food additive regulations and their amendments adopted under authority of the federal act are the food additive regulations in this state. However, the department may adopt regulations which prescribe conditions under which a food additive may be used in this state which are no less stringent than regulations promulgated under the federal act.
- (5) All color additive regulations and their amendments adopted under authority of the federal act are the color additive regulations in this state. However, the department may adopt regulations which prescribe conditions under which a color additive may be used in this state which are no, less stringent than regulations promulgated under the federal act.
- (6) All special dietary use regulations and their amendments adopted under authority of the federal act are the special dietary use regulations in this state. However, the department may, if it finds it necessary to inform purchasers of the value of a food for special dietary use, prescribe special dietary use regulations which are no less stringent than regulations promulgated under the federal act.
- (7) All regulations and their amendments adopted under the federal "Fair Packaging and Labeling Act" shall be the regulations in this state. However, the department may, if it finds it necessary in the interest of consumers, prescribe packaging and labeling regulations for consumer commodities which are no less stringent than regulations promulgated under such "Fair Packaging and Labeling Act", but no such regulations shall be promulgated which are contrary to the labeling

requirements for the net quantity of contents required pursuant to the "Fair Packaging and Labeling Act" (15 U.S.C. 1453) and the regulations promulgated thereunder.

(8) All regulations establishing standards of identity and composition for meat and meat food products and their amendments adopted under the federal "Meat Inspection Act of March 4, 1907", as amended (21 U.S.C. 71-91), are the established standards of identity and composition for meat and meat food products in this state. However, the department may, if it finds it necessary in the interest of consumers, adopt additional regulations establishing standards of identity and composition for meat and meat food products which are no less stringent than regulations promulgated under the federal "Meat Inspection Act".

- (g) (a) A federal regulation automatically adopted pursuant to this part 4 takes effect in this state on the date it becomes effective as a federal regulation. The department shall publish all other proposed regulations thirty days prior to hearing thereon. A person who may be adversely affected by a regulation may file with the department, in writing, objections and a request for a hearing. The timely filing of substantial objections to a federal regulation automatically adopted stays the effect of the regulation in this state.
- (b) If no substantial objections are received and no hearing is requested within thirty days after publication of a proposed regulation, it shall take effect on a date set by the department. The effective date shall be at least sixty days after the time for filing objections has expired.
- (c) If substantial objections are made to a federal regulation within thirty days after it is automatically adopted or to a proposed regulation within thirty days after it is published, the department, after notice, shall conduct a public hearing to receive evidence on the issues raised by the objections. Any interested person or his representative may be heard. The department shall act upon objections by order and shall mail the order to objectors by certified mail as soon after the hearing as practicable. The order shall be based on substantial evidence in the record of the hearing. If the order concerns a federal regulation, it may reinstate, rescind, or modify such regulation. If the order concerns a proposed regulation, it may withdraw it or set an effective date for the regulation as published or as modified by the order. The effective date shall be at least sixty days after publication of the order.
- 25-5-421. INSPECTIONS. (1) (a) For purposes of enforcement of this part 4, the authorized agents of the department, upon presenting appropriate credentials to the owner, operator, or agent in charge, are authorized to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce or are held after such introduction, or ,to enter any vehicle

being used to transport or hold such food, drugs, devices, or cosmetics in commerce; and to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein and to obtain samples necessary to the enforcement of the part 4.

(b) (I) In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this part 4 or which may not be manufactured, introduced into commerce, or sold or offered for sale by reason of any provision of this part 4 have been or are being manufactured, processed, packed, transported, or held in any such place or otherwise bearing on violation of this part 4.

- (II) No inspection authorized for prescription drugs by subparagraph (I) of this paragraph (b) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this article), and research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to 21 U.S.C. 355 (I) or (j) and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under regulations issued pursuant to 21 U.S.C. 355 (j)). Each such inspection shall be commenced and completed with reasonable promptness.
- (III) The provisions of subparagraph (I) of this paragraph (b) shall not apply to pharmacies which maintain establishments in conformance with the laws of this state regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail; to practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice; to persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale; nor to such other classes of persons as the department may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.
- (c) The authorized agents of the department, upon presenting appropriate credentials to the owner, operator, or agent in charge, are authorized to have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; but evidence, obtained under this paragraph (c) shall not be used in a criminal prosecution of the person from whom obtained, and carriers shall not be subject to the other provisions of this part 4 by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.
- (2) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device or cosmetic in such establishment consists in whole or in part of any filthy, putrid, or decomposed substance or has been prepared, packed, or held under unsanitary conditions under

which it may become contaminated with filth or rendered injurious to health. A copy of such report shall be sent promptly to the department.

- (3) If the authorized agent making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.
- (4) Whenever, in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.
- 25-5-422. REPORTS AND INFORMATION. (1) The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this part 4, including the nature of the charge and the disposition thereof.
- (2) The department may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the department deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the department from collecting, reporting, and illustrating the results of the investigations of the department.
- 25-5-423. COOPERATION WITH FEDERAL AGENCIES. The department is authorized to confer and cooperate with the federal Food and Drug Administration in the enforcement of the federal act and the United States Department of Agriculture in the enforcement of the federal "Meat Inspection Act of 1907", as amended, as they may apply to foods, drugs, devices, and cosmetics received in this state from other states, territories, or foreign countries.
- 25-5-424. REVIEW. Any person aggrieved by a decision of the department, and affected thereby, is entitled to judicial review pursuant to section 25-1-113.
- 25-5-425. APPLICATION OF PART 4. The powers in this part 4 vested in the department are declared to be cumulative and in addition to and not in exclusion nor derogation nor limitation of the powers vested by law in the department, or in any other department of this state, or in any board or commission established by law, or in any law enforcement authority of this state.

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